Applicant: Stoughton et al. Attorney Docket No.: 17124-003001/2202

Serial No.: 09/038,894
Filed: March 11, 1998
Amendment and Response

CLAIM AMENDMENTS

Please amend claims 10, 11, 13, 15 and 32 as follows. This listing of claims replaces all prior versions, and listings of claims, in the application.

Listing of Claims:

Claims 1-9 Cancelled.

10. (Currently Amended) A method of improving treatment outcome or reducing risk of treatment for a disease or condition, comprising:

assessing treatment options for <u>treatment of</u> a disease or condition <u>in a subject</u>; by measuring <u>the level of activation of white blood cells</u> cell activation levels in a subject with the disease or condition; and,

determining if the level of activation is elevated;

if <u>the level of</u> cell activation <u>levels are is</u> elevated, administering activation lowering therapy prior to commencing treatment for the disease or condition <u>or with treatment for the disease or condition</u>, thereby improving treatment outcome or reducing risk of <u>the</u> treatment <u>for the disease or condition</u>; and

administering treatment for the disease or condition.

- 11. (Currently Amended) The method of claim 10, wherein cell activation is measured assessed by assays that measure one or more of the level of free radical production, pseudopod formation, adhesion molecule expression and degranulation.
- 12. (Original) The method of claim 10, wherein the disease or condition treated is selected from cardiovascular disease, inflammatory disease, trauma, autoimmune diseases, arthritis, diabetes and diabetic complications, stroke, ischemia and Alzheimer's disease.
- 13. (Currently Amended) The method of claim 10, wherein the treatment being assessed for the disease or condition is surgery, treatment of unstable angina or treatment for trauma.
- 14. (Original) The method of claim 10, wherein activation lowering therapy comprises administering a protease inhibitor, dialysis, alterations in lifestyle to reduce stress, or alterations in diet.
- 15. (Currently Amended) The method of claim 14, wherein:
 the cell activation lowering therapy comprises administering a the protease inhibitor;
 and

the protease inhibitor is a serine protease inhibitor.

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16. (Original) The method of claim 14, wherein the protease inhibitor is selected from among α_1 -proteinase inhibitor (α_1 -antitrypsin), α_2 -macroglobin, inter- α_1 -trypsin inhibitor, and α_1 -antichymotrypsin.

- 17. (Previously Amended) The method of claim 10, wherein the disease or condition is selected from the group consisting of myocardial infarction, stroke, hemorrhagic shock, diabetic retinopathy, diabetes and venous insufficiency.
- 18. (Original) The method of claim 14, wherein the protease inhibitor is 6-amidino-2-naphthyl p-guanidinobenzoate dimethanesulfonate or a pharmaceutically acceptable salt, acid, ester and other derivatives thereof.

Claims 19-31 (Cancelled).

32. (Currently Amended) A method, comprising:

assessing testing cell activation level of white blood cells in a subject;

determining if the level is elevated; and,

if the white blood cell activation level is elevated, administering <u>or undertaking cell</u> activation lowering therapy to lower the level of cell activation, thereby preventing a disease or disorder or reducing the risk of a poor outcome of a treatment of a disease or disorder.

- 33. (Original) The method of claim 32, wherein activation lowering therapy comprises modifications in diet and/or lifestyle.
- 34. (Original) The method of claim 32, wherein activation lowering therapy comprises administration of a protease inhibitor.
- 35. (Original) The method of claim 34, wherein the protease inhibitor is a serine protease inhibitor.
- 36. (Original) The method of claim 34, wherein the protease inhibitor is selected from among α_1 -proteinase inhibitor (α_1 -antitrypsin), α_2 -macroglobin, inter- α_1 -trypsin inhibitor, and α_1 -antichymotrypsin.

Claim 37 (Cancelled).

38. (Original) The method of claim 32, wherein activation lowering therapy comprises dialysis.

Claims 39 and 40 (Cancelled).

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41. (Previously presented) The method of claim 34, wherein the protease inhibitor is 6-amidino-2-naphthyl p-guanidinobenzoate dimethanesulfonate or a pharmaceutically acceptable salt, acid, ester and other derivatives thereof.

42. (Previously presented) The method of claim 32, wherein cell activation is assessed by assays that measure one or more of the level of free radical production, pseudopod formation, adhesion molecule expression and degranulation.